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EXAMINER

KAUSHAL, SUMESH

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.



### **DETAILED ACTION**

Applicant's response filed on 01/22/08 has been acknowledged and fully considered.

Claims 1-16, 20-29 and 48-54 are pending and are examined in this office action.

This application contains claims 20-29 and 51-53 are drawn to an invention nonelected with traverse in the reply filed on 08/14/07. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Note: Earlier applicant elected Group I claims 1-16 and 48-50. Therefore, claims 1-16, 48-50 and 54 are examined in this office action, whereas claims 20-29 and 51-53 that represented Group III stand withdrawn from further consideration.

Applicants are required to follow Amendment Practice under revised 37 CFR §1.121. The fax phone numbers for the organization where this application or proceeding is assigned is **571-273-8300**.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The references cited herein are of record in a prior Office action.

### ***Claim Rejections - 35 USC § 102***

Claims 1, 4-6, 9, 16, 48-50 and 54 are rejected under 35 U.S.C. 102(b) as being anticipated by Vasa et al (Circ. Res. 89(1):E1-7, 2001, ref. of record on PTO-1449), for the reason of record as set forth in the office action mailed on 10/30/07.

### **Response to Argument**

The applicant argues that Vasa et al. (Circ. Res.) does not anticipate, nor render obvious the instant claims as all the subjects in cited art have coronary artery disease and the art does not suggest, nor render obvious that a decrease in the number of EPCs will affect vascular function, let alone vascular function in subjects without coronary artery disease.

However the applicant's arguments are found not persuasive. As stated earlier Vasa et al. (Circ. Res.) clearly teaches number and migratory activity of circulating Endothelial Progenitor Cells (EPCs) inversely correlate with risk factors for coronary artery disease (CAD). The cited art teaches the isolation and enumeration of EPCs from the peripheral blood of patients with coronary artery disease (CAD) and compared the results to a control sample (see abstract, page 4, fig(s) 2-4). The applicant fails to consider that the cited art clearly teaches that that several experimental studies indicate a significant contribution of EPCs for adult neovascularization (increased vascular function), the reduction in the number of EPCs and their functional impairment might contribute to reduced vascularization in patients with CAD. The cited art further teaches that age (senescence), hypertension, smoking, cholesterol levels, and a positive family of CAD, as well as the overall number of risk factors, have all been shown to be associated with impaired endothelium-mediated vasodilator function of the coronary circulation. Therefore, one may speculate that the impairment of circulating EPCs may contribute to an insufficient regeneration of the endothelium, which may lead to endothelial dysfunction (page 6, col.1 para 1, table-1).

"[I]n considering the disclosure of a reference, it is proper to take into account not only specific teachings of the reference but also the inferences which one skilled in the art would reasonably be expected to draw therefrom." *In re Preda*, 401 F.2d 825, 826, 159 USPQ 342, 344 (CCPA 1968). In instant case the cited art clearly anticipate the invention as claimed because the composition and functions as claimed are presumed inherent (i.e. increased vascular function as a result of EPC modulation). The composition is physically the same it must have the same properties. "Products of identical chemical composition can not have mutually exclusive properties." A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. *In re Spada*, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990) see MPEP § 2112.02. Thus the cited art clearly anticipates the invention as claimed.

Claims 9-11 and 16 are rejected under 35 U.S.C. 102(b) as being anticipated by Vasa et al (Circulation. 103(24):2885-90, 2001, ref. of record on PTO-1449), for the reason of record as set forth in the office action mailed on 10/30/07.

### **Response to Argument**

The applicant argues that Vasa et al. does not suggest that a decrease in the number of EPCs would lead to a decrease in vascular function, such as vascular contractility, brachial reactivity, arterial hyperplasia or morphometric parameters. The applicant argues that cited art does test the effect of statin treatment in healthy subjects, but this is only as a control population. The applicant argues that cited art does not suggest, nor render obvious assessing vascular function in either the subjects with stable CAD or the control. The applicant continues that the cited art does not suggest that changes in the number of EPCs have any effect in the healthy controls.

However the applicant's arguments are found not persuasive because the cited art clearly teaches that there is an increase in circulating EPCs by statin therapy in patients with stable coronary artery disease (CAD). The cited art teaches enumeration of EPCs in patients treated with blood cholesterol lowering agent atorvastatin (page 2888 fig-3, fig-4). The cited art demonstrated that statin therapy is associated with an increase in the number of circulating EPCs in patients with stable CAD. The applicant fails to consider that the cited art clearly teaches the isolation and enumeration of EPCs from the peripheral blood of patients with coronary artery disease (CAD) and compared the results to a control sample (see page 2887, fig-2A). The cited art further teaches that the results of the present study demonstrate that statin therapy is associated with an increase in the number of circulating EPCs in patients with stable CAD. The increased number of EPCs was paralleled by an enhancement of the migratory capacity of isolated EPCs. Mobilization of circulating EPCs with enhanced functional activity might contribute to the well-established beneficial effects of statins in patients with CAD as it is well established that EPCs participate in repair after ischemic injury (page 2889, col.1 para. 2). The cited art further teaches that statin therapy has shown to rapidly enhance coronary blood flow (an increased vascular function) in patients with stable CAD and to reduce myocardial ischemia (an increased vascular function) after an acute

Art Unit: 1633

ischemic episode within a few weeks of treatment (page 2889, col.2 para. 4). The cited art clearly teaches that the mobilization of circulating EPCs is associated with enhanced functional activity which leads to neovascularization (see page 2885, col.1 para.2 col.2). The cited art further states that finding that statin therapy also increases EPC levels in healthy volunteer, whereas EPC levels remained unchanged in the untreated healthy control group, support the hypothesis that statin directly effects EPC levels which in turn is capable of enhancing the vascular function i.e. neovascularization, ischemic repair (see Page 2889 col.1-2).

"[I]n considering the disclosure of a reference, it is proper to take into account not only specific teachings of the reference but also the inferences which one skilled in the art would reasonably be expected to draw therefrom." *In re Preda*, 401 F.2d 825, 826, 159 USPQ 342, 344 (CCPA 1968). In instant case the cited art clearly anticipate the invention as claimed because the composition and functions as claimed are presumed inherent (i.e. increased vascular function as a result of EPC modulation). The composition is physically the same it must have the same properties. "Products of identical chemical composition can not have mutually exclusive properties." A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. *In re Spada*, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990) see MPEP § 2112.02. Thus the cited art clearly anticipates the invention as claimed.

### ***Claim Rejections - 35 USC § 112***

Claims 2-3, 7-8, 12-15 and 48-50 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, for the reason of record as set forth in the office action mailed on 10/30/07.

Claim 2 and 12 are indefinite. The applicant argues that instant calims has been amended to overcome current rejection. However the applicant's arguments are found

not persuasive because as stated earlier it is unclear how the number of endothelial progenitor cells that elicits any phenotypic markers are assayed by merely subjecting a mixed population of non-adherent blood cells obtained from buffy coat to any and all kind culture conditions that leads to any and all kinds of colonies derived from any and all kind of cells present in the blood cell preparation as claimed.

Claim 48-50 are indefinite. The applicant argues that instant claims have been amended to overcome current rejection. However the applicant's arguments are found not persuasive it is unclear what is the "senescent endothelial progenitor cells... wherein... cell is viable endothelial cell that can not divide". The instant claim fails to recite any phenotypic feature that would distinguish the invention as claimed in view of a non-senescent endothelial progenitor cell.

Examiner reviewing application for compliance with 35 USC 112, second paragraph, can require that invention be described in terms sufficiently definite to enable comparison with available art, since it is essential to know what claims in fact cover before such comparison can be properly made. *Ex parte Tanksley*, 26 USPQ2d 1384 (Bd. Pat. App. & Int. 1991). In the instant case at issue is the phenotypic markers of the cells recited in the instant claims, since it is essential to know what claims in fact cover before such comparison can be properly made.

### ***Conclusion***

No claims are allowed

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the

Art Unit: 1633

shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

/Sumesh Kaushal/  
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